REMARKS

Claims 1-43 are pending in the Application and claims 20-43 are withdrawn from consideration in view of the restriction requirement of October 23, 2009, thereby leaving claims 1-19 presently under consideration. Notwithstanding this, the withdrawn claims are also corresponding amended so that such claims may possibly be reinstated in the above identified application in due course.

The Examiner rejects claims 7-9 and 17-19 as indefinite under 35 U.S.C. 112. second paragraph, referring specifically to the appearance of the terms "substantially", "generally" and "sufficiently short" in claims 7, 8, 17 and 18, the recitation "curved so as to conform generally with a curvature of a face of a patient" in claims 8 and 18, and the terms "sufficient stiffness" and "urged" in claims 9 and 19. In response, the claims 8 and 18 are canceled, without prejudice to or abandonment of the subject matter therein, while claims 7, 9, 17 and 19 are suitably amended to address and overcome the stated grounds for rejection of those claims under 35 U.S.C. 112. It will be noted that these claim amendments are fully supported by the specification and the claims as originally filed and that these amendments do not add any new matter to or altered the subject matter of the invention, the specification or the claims. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of the claims under 35 U.S.C.112.

Next, claims 1 and 11 are rejected, under 35 U.S.C. 102, over U.S. Patent No. 4,648,398 to Agdanowski et al., hereinafter referred to as "Agdanowski et al. `398", while claims 2-10 and 12-19 are rejected, under 35 U.S.C. 103, over Agdanowski et al. `398 in view of U.S. Patent No. 5,105,807 to Kahn et al., hereinafter referred to as "Kahn et al. `807". The Applicant acknowledges and respectfully traverses both of the raised rejections in view of the above amendments and the following remarks.

First considering the claims, it will be noted that claims 1 and 11 are independent claims and that claims 3-7, 9, 10 and 13-17 and 19 all depend from either claim 1 or claim 11, so that claims 2-10 and 12-19 each include all elements and limitations recited in either independent claim 1 or claim 11, respectively. It will also be noted that independent claims 1 and 11 are amended by the above to more clearly and explicitly recite the present invention, while claims 2, 8, 12 and 18 are canceled without prejudice from the above identified application. It will also

be noted that the dependencies of claims 3-7, 9, 10, 13-17 and 19 are amended to accommodate the cancellations of claims 2, 8, 12 and 18.

Turning now to the applied art, it is respectfully submitted that the presently pending claims are patentably different from the teachings of Agdanowski et al. `398 in that this reference fails to teach a nasal cannula comprising a pair supply lines with heads which are formed integrally with and from the same material as the supply lines, as presently claimed. This distinction, between the presently claimed invention and the teachings of the cited reference, will be discussed in more detail below.

Now considering the present invention as recited in independent claims 1 and 11, and as thereby incorporated into the recitations of claims 3-7, 9, 10, 13-17 and 19, the present invention is directed to a nasal cannula and a nasal cannula assembly for supplying a respiratory gas to a patient. As recited in claims 1 and 11, the nasal cannula comprises a pair of supply lines each of which has a head located adjacent a leading end thereof. The supply lines have with a discharge opening therein for discharging a respiratory gas into the nasal cavity of the patient while the opposite end of each of the pair of supply lines is connected to a respiratory gas source. Each of the heads is formed integral with and from the same material as the supply line and the outer surface of the head is sized to be snugly received and retained within one of the nasal cavities of the patient. A plurality of leakage passages are formed between an exterior surface of the head and the nasal passage, e.g., the exterior surface of the head has a plurality elongate troughs which together with the inwardly facing nasal cavity skin of a patient partially define the plurality of leakage passages. The leakage passages facilitate exhausting excess respiratory gas that is supplied to the patient through the leakage passage while maintaining a positive pressure within a respiratory passage of the patient at least during exhalation by the patient.

Turning now to the applied art of Agdanowski et al. `398, this reference relates to a nasal cannula 16 having two conduits 18, 20, the distal ends 42, 44 of which are secured by a bridge member 28 such that the distal ends 42, 44 of the conduits 18, 20 are arranged to be inserted into a patient's nose. The distal ends 42, 44 of the conduits 18, 20 are provided with annular flanges 46, 48 which are utilized to retain seals 34, 36. Each of the seals 34, 36 has a through hole 38, 40 through which the distal ends 42, 44 of the conduits 18, 20 extend. The

seals 34, 36 are disclosed as being a *separate*, soft, compressible, resilient foam or sponge like. While the of the seals 34, 36 may have any of a variety of exterior shapes or contours–such as shown in Figs. 4-7 of Agdanowski et al. `398–the seals 34, 36 are compressed to a size less than the patient's nostrils to facilitate insertion into the patient's nostrils.

Once inserted into the patient's nostrils, the seals 34, 36 then expand to *form a seal between the exterior surface of the tip seal and the inwardly facing or inner surface of the patient's nostrils* and, as described at column 3, lines 11-15 of Agdanowski et al. `398. In addition to retaining the nasal tips in the patient's nostrils, the tip seals also generally prevent the flow of air or gas in or out of the nostrils except through the air flow tubes or conduits extending through the tip seals. It is possible to make the seals 34, 36 from a variety of sponge-like or foam materials that provide the desirable characteristics of specific rates of recovery in a given period of time after compression. The conduits 42, 44 may be formed of a suitable plastic such as polyvinyl chloride such that the conduits 42, 44 are relatively stiff to prevent inadvertent bending.

It is therefore apparent that there are a number of fundamental distinctions between the teachings of Agdanowski et al. `398 and the present invention as recited in claims 1 and 11 and as thereby recited in dependent claims 3-7, 9, 10, 13-17 and 19. For example, according to the presently claimed invention, as recited in claims 1 and 11, the exterior surface of each cannula head has a plurality elongate troughs formed therein for partially defining a plurality of leakage passages between a portion of the inwardly facing nasal cavity skin of the patient and a portion of an exterior surface of the head. The leakage passages formed around each cannula head by the troughs in the exterior surfaces of the cannula heads are, in fact, a major feature of the present invention and facilitate exhausting of excess respiratory gas supplied to the patient through the leakage passages while still maintaining a positive pressure within a respiratory passage of the patient at least during exhalation by the patient. The Agdanowski et al. `398 device, in complete and fundamental contrast from the present invention, does not intentionally provide any such leakage path or passage and the Agdanowski et al. `398 device is, in fact, specifically designed to prevent such leakage paths by forming a seal between the nasal tips and the patient's nostrils.

In this regard, and in further fundamental distinction between the present invention as recited in the claims and the teachings of Agdanowski et al. `398, the presently claimed cannula and cannula assembly has a plurality of troughs formed in the exterior surfaces of the cannula heads and the cannula heads are formed of a material that is only slightly resilient--if at all--so that leakage paths spaced around the cannula heads are formed when the cannula heads are inserted into the patient's nostrils. In complete contrast from the present invention, the Agdanowski et al. `398 device not only does not have troughs formed in the exterior surfaces of the nasal tips, for forming leakage paths when inserted into the nostril of the patient, but the nasal tips are fabricated from a resilient foam-like material–which is separate and distinct from a remainder of the cannula–so that the nasal tips expand, after insertion into the patient's nostrils, to form a seal around each nasal tip between the nasal tip and the interior surfaces of the patient's nostrils.

In addition, and because the nasal heads of the present invention comprise a material that is at most slightly compressible, the cannula and cannula assembly of the present invention do not rely upon a change in the dimensions of the cannula heads to secure the cannula heads within the patient's nostrils. As a result, the dimensions of the leakage passages, in the outer surface of the cannula heads, can be sufficiently controlled so as to achieve the desired object, that is, allow leakage of excess gas while still retaining the heads securely positioned within the nostrils and thereby to maintain a positive pressure in the patient's respiratory system during use. In distinct contrast, it is respectfully submitted that even if the Agdanowski et al. `398 were to be provided with longitudinal grooves in the nasal tips, the reliance of the Agdanowski et al. `398 device upon the compression/expansion of the nasal tips, to fit the nasal tips into the patient's nostrils, would generally prevent the formation of any trough(s) in the external surface of the compressible nasal tips which could be controlled so as to perform the leakage passage function of the cannula heads according to the presently claimed invention.

Further, the pending claims recite that the heads are formed from *the same material as the pair of supply lines*. This feature of the claims is in direct contrast to the specific teachings, suggestions, disclosures and/or hints of Agdanowski et al. `398 which describe the seals as being made of a compressible foam or sponge-like material while the conduits are made of a relatively stiff plastic material.

It is therefore apparent that for at least the reasons discussed above, Agdanowski et al. `398 fails to in any way teach, suggest, disclose or remotely hint at the presently claimed invention, as recited in claims 1 and 11, and as thereby recited in dependent claims 3-7, 9, 10, 13-17 and 19, to those of ordinary skill in the arts under the requirements and provisions of 35 U.S.C. 102 or 35 U.S.C. 103 and, in fact, teaches directly away from the present invention as recited in the claims. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims 1 and 11, as well as dependent claims 3-7, 9, 10, 13-17 and 19, under 35 U.S.C. 103 in view of Agdanowski et al. `398, and allow claims 1 and 11 and dependent claims 3-7, 9, 10, 13-17 and 19 as presented herein above.

Turning now to the teachings of Kahn et al. `807 and the combination of Agdanowski et al. `398 and Kahn et al. `807, Kahn et al. `807 relates to a device for retaining a nasal tube in a patient's nostril. This device includes the nasal tube 5, a support tube 1, a compressible sleeve 2 and a locking device 4. Each of the support tube 1 and the compressible sleeve 2 have a passage 14 along their length such that the nasal tube 5 can be passed therethrough into the interior of the nasal tube 5. One inserted into the nasal tube 5, the locking device 4 is adjusted so as to lock the nasal tube 5 in place with respect to the support tube 1 and the compressible sleeve 2. According to Kahn et al. `807, the compressible sleeve 2 is mounted onto the support tube 1 and the nasal tube 5 is secured into the passage through the support hub 3 so that the nasal tube 5 extends lengthwise through the support hub 3 and tube 1. The compressible sleeve 2 with the nasal tube 5 extending therethrough is inserted into a patient's nostril and the compressible sleeve 2 is then allowed to expand to meet with the interior surface of the patient's nostril–in generally the same manner as the nasal tips of the Agdanowski et al. `398 device–thereby securing the nasal tube 1 and compressible sleeve 2 in the patient's nostril.

As illustrated in Figs. 3a-3e and 4a-4g and as described in column 4, lines 16-22 and column 5, lines 29-43 of Kahn et al. `807 for example, the nasal tube 1 has a smaller diameter than the passage 14 through the support tube 1 to thereby provide a passageway through and around the device and nasal tube 1 for draining and discharge of nasal fluids, and the compressible sleeve 2 may include a number of longitudinal passages or grooves extending either through the compressible sleeve (Fig. 4f) or on the exterior surface (Fig. 4g) of the

compressible sleeve to provide a number of additional passageways for the draining and discharge of nasal fluids.

It is clear from the Figures of the reference that the each of the components of the device, i.e., the nasal tube 5, the support tube 1, the compressible sleeve 2 and the locking device 4 is made from a different material. Each component has a different function and is made from a material that would be best for facilitating that function. For example, the compressible sleeve is made from a soft, sponge-like foam or rubber material such that the sleeve can be compressed and inserted into a patient's nostril after which the sleeve will re-expand and contact with the inside of the patient's nostril and retain the device therein. The support tube on the other hand is made of plastic or other suitably rigid material such as ceramic, rubber or metal such that the support tube can support the locking device to rigidly retain the nasal tube in place with respect to the device.

The Applicant respectfully submits that the pending claims are distinct from the teachings of Kahn et al. `807 in that this reference fails to teach a nasal cannula comprising a pair supply lines with heads formed integrally with and from the same material as the supply lines, as presently claimed. This distinction between the pending claims and the teachings of the cited reference will be discussed in more detail below.

It is therefore apparent that there are a number of fundamental distinctions between the present invention as recited in claims 1 and 11, and as thereby recited in claims 3-7, 9, 10, 13-17 and 19. For example, the passageways in the Kahn et al. `807 device between the compressible sleeve and the support tube and through the troughs around the circumference of the compressible sleeve may appear to have some relationship to the leakage passages formed around each cannula head according to the present invention, as recited in claims 1 and 11. This, however, is a misleading resemblance as the purpose and functions of the passageways in the Kahn et al. `807 device are fundamentally different from those of the presently claimed invention and these differences are reflected in the structures of the cannula heads, as presently claimed, when compared to the Kahn et al. `807 reference.

That is, and as recited in claims 1 and 11 and as described in the present application, the purpose and function of the troughs in the exterior surfaces of the cannula heads in the present invention are to facilitate exhausting of excess respiratory gas from the patient's

respiratory system while still maintaining a positive pressure within a respiratory passage of the patient, at least during exhalation by the patient, so as to maintain the patient's respiratory passages in an inflated substantially "open" state. In complete and fundamental contrast to the present invention, however, and as described by Kahn et al. `807 at, for example, column 4, lines 20-25 and 28-42, the disclosed purpose of the passageways through and around the compressible sleeve is to provide a means for draining and discharging nasal fluids and gastric fluids from the nasal passages of the patient and, as described for example, at column 6, line 65 to column 7, line 3, to provide a passageway of sufficient size to allow normal air movement and breathing by the patient and to prevent the device from being dislodged from the patient's nostril by, for example, normal breathing, coughing, sneezing, and so on by the patient.

It is therefore apparent that the Kahn et al. `807 device does not and cannot perform at least one of the primary functions of the cannula and cannula assembly according to the present invention which, as recited in claims 1 and 11 and as thereby recited in the dependent claims, is to maintain a positive pressure within a respiratory passage of the patient, at least during exhalation by the patient, so as to maintain the patient's respiratory passages in an inflated and open state.

It is quite clear that in the Kahn et al. `807 device, and because the passageways through and around the compressible sleeve are specifically required to be of a size to allow free breathing and air movement and to prevent a positive pressure within the patient's nostril, whether from normal breathing or from coughing or sneezing, from dislodging the nasal tube, the Kahn et al. `807 device thus fails to in any way teach, suggest, disclose or remotely hint at the functions of the nasal cannula and cannula assembly of the present invention. In fact and in at least this regard, it is respectfully submitted that Kahn et al. `807 teaches directly away from the presently claimed invention.

It must also be noted that the Kahn et al. `807 device is further fundamentally distinguished from the present invention because the nasal cannula and cannula assembly of the present invention, as recited in the claims, are designed and structured to supply only gases to the patient's respiratory system. In complete contrast, the Kahn et al. `807 is designed to delivery both gases and fluids, such as gastric system fluids, to the patient, and this fundamental distinction is reflected in the structures and features of the two devices.

In further distinction between the present invention, as recited in the claims, and the teachings of Kahn et al. `807, it must be noted that, like the nasal tips of the Agdanowski et al. `398, the compressible sleeve of the Kahn et al. `807 device is formed from a compressible material that is compressed in order to insert the device into a patient's nose and then released so as to expand and secure the device in the patient's nose. As discussed above, the nasal heads of the present invention comprise a material that is at most slightly compressible, so that the cannula and cannula assembly of the present invention generally does not rely upon a change in dimension of the cannula heads to secure the cannula heads in the patient's nostrils, thereby allowing the dimension of the leakage passages in the outer surface of the cannula heads to be controlled sufficiently to achieve the desired object, that is, allow leakage of excess gas while still maintaining a positive pressure in the patient's respiratory system. According to the Kahn et al. `807 device, however, and because the Kahn et al. `807 device relies on a change in the dimension of the compressible sleeve to secure the device in the patient's nostril, it is respectfully submitted that the dimensions of the longitudinal grooves in the compressible sleeve cannot be adequately controlled to a degree sufficient to provide the functions of the present invention, that is, to allow the exhaust of excess gas while maintaining a positive pressure in the patient's respiratory system.

In still further distinction between the present invention as recited in the claims and the teachings of Kahn et al. `807, it must be noted that, as described herein above as recited in claims 1 and 11 and as thereby recited in the dependent claims, the cannula and cannula assembly of the present invention is provided with two gas supply lines, each of which is provided with a cannula head, so that the cannula and cannula assembly of the present invention can concurrently provide gas to both of the patient's nostrils. In complete contrast from the cannula and cannula assembly of the present invention, however, not only does Kahn et al. `807 describe its device as only having a single gas or liquid supply tube connected to a single device inserted into only one of the patient's nostrils, but it is apparent from the illustrations of the Kahn et al. `807 device that the size and configuration of the hub and support tube assembly would generally avoid and/or prevent the use a supply line to each of the patient's nostrils, that is, would prevent the system from using two supply lines concurrently as with the presently claimed invention and the applied art of Agdanowski et al. `398.

Finally, the claims of the application recite that *the heads are formed from the same material as the pair of supply lines*. This feature of the claims is in direct contrast to the teachings of Kahn et al. `807 which describes the sleeves as being made of a compressible foam or sponge-like material while the nasal tubing is some other material. The sleeves are completely independent from the nasal tubing. There are a number of benefits of the claimed nasal cannula over the cited references. The device for securing nasal tubing, as taught by Kahn et al. `807, is made from a number of independent components, each of which is made separate from the others. As such each of these elements must be assembled with one another before the device is ready for use. It is respectfully submitted that these extra steps increases the manufacture time and associated manufacturing costs. In distinct contrast, as the components of the claimed nasal cannulas are integral and formed from a single material, the associated manufacturing and assembly costs are generally less.

It is therefore apparent that for at least the reasons discussed above, Kahn et al. `807 fails to in any way teach, suggest, disclose or remotely hint at the presently claimed invention, as recited in claims 1 and 11 and as thereby recited in dependent claims 3-7, 9, 10, 13-17 and 19, to those of ordinary skill in the arts under the requirements and provisions of 35 U.S.C. 103 and, in fact, teaches directly away from the present invention as recited in the claims. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims 1 and 11 and dependent claims 3-7, 9, 10, 13-17 and 19, under 35 U.S.C. 103, over Kahn et al. `807, and allow claims 1 and 11 and dependent claims 3-7, 9, 10, 13-17 and 19 as presented herein above.

Lastly considering the combination of Agdanowski et al. `398 in view of Kahn et al. `807, it is respectfully submitted that first it would not be apparent to one of ordinary skill in the relevant arts to combine the teachings of Agdanowski et al. `398 and Kahn et al. `807 because the teachings of Agdanowski et al. `398 and Kahn et al. `807 generally teach away from one another. For example, while both Agdanowski et al. `398 and Kahn et al. `807 use compressible and expandable nasal tips of sleeves to secure the nasal tubes into the patient's nostrils, Agdanowski et al. `398 teaches that the nasal tips should *seal to the inside surfaces of the patient's nostrils to prevent the flow or leakage of gas past the nasal tips*. In complete contrast, Kahn et al. `807 teaches that *the compressible sleeves*, which serve essentially some

of the same purposes as the nasal tips of Agdanowski et al. `398, *should have at least a passage through the sleeve, between the sleeve and support tube, and often should have a number of longitudinal grooves on the surface of the sleeve to provide additional passages.* It is therefore the Applicant's position that the combination of Agdanowski et al. `398 and Kahn et al. `807 is generally improper because teachings of the two references are fundamentally in conflict with one another and, in fact, each away from one another. Moreover, the only reference relating to the combination of features alleged by the Examiner is the above identified application. Accordingly, it is respectfully submitted that the suggested combination of Agdanowski et al. `398 and Kahn et al. `807 appears to be improperly based upon hindsight and the teachings of the present invention rather than on the teachings found in either the Agdanowski et al. `398 and/or Kahn et al. `807 references.

Considering the combination of Agdanowski et al. `398 and Kahn et al. `807, however, and solely for purposes of discussion and without any admission or agreement by the Applicant regarding the validity of such a combination, it is clearly apparent that the compressible sleeve described by Kahn et al. `807 is the only element from Kahn et al. `807 that might be combined with Agdanowski et al. `398. It must be recognized, however, that this combination ignores, solely for this purpose and for purposes of discussion, the fundamental conflict between Agdanowski et al. `398 and Kahn et al. `807 with regard to the structure and function of the Agdanowski et al. `398 nasal tips and the Kahn et al. `807 compressible sleeve.

If such a combination were attempted, it is respectfully submitted that the resulting combination would be no more than what is already taught by Agdanowski et al. `398 and Kahn et al. `807 individually, with the exception that it may be possible to have a supply line to each of the patient's nostrils given the elimination of the Kahn et al. `807 support hub and support tube elements. It must be noted that this combination would eliminate the passage between the compressible sleeve and the support tube as found in the Kahn et al. `807.

In addition, and depending upon the specific implementation of the compressible sleeve, the compressible sleeve may be designed to fit into the patient's nostrils sufficiently tightly to form a seal between the sleeves and the patient's nostrils, according to the teachings of Agdanowski et al. `398 and contrary to the teachings of Kahn et al. `807. In this case, the present invention, as recited in the pending claims, is fundamentally distinguished over and

from the combination for the same reasons that the present invention as recited in the claims is patentably distinguished over and from the teachings of Agdanowski et al. `398 for the reasons discussed above with respect to Agdanowski et al. `398.

In the alternative, the compressible sleeve may be designed to fit into the patient's nostrils according to the teachings of Kahn et al. `807, that is, so as to provide passageways around the device, contrary to the teachings of Agdanowski et al. `398. In this case, however, the present invention as recited in the claims is fundamentally distinguished over and from the combination for the same reasons that the present invention as recited in the claims is patentably distinguished over and from the teachings of Kahn et al. `807 for the reasons discussed above with respect to Kahn et al. `807.

It is therefore apparent that for at least the reasons discussed above, the combination of Agdanowski et al. `398 and Kahn et al. `807 fails to in any way teach, suggest, disclose or remotely hint at the present invention, as recited in claims 1 and 11 and as thereby recited in dependent claims 3-7, 9, 10, 13-17 and 19, to those of ordinary skill in the arts under the requirements and provisions of 35 U.S.C. 103 and, in fact, teaches directly away from the present invention as recited in the claims. The Applicant therefore respectfully requests that the Examiner reconsider and withdraw all rejections of claims 1 and 11 and dependent claims 3-7, 9, 10, 13-17 and 19, under 35 U.S.C. 103, over the combination of Agdanowski et al. `398 and Kahn et al. `807 and allow claims 1 and 11 and dependent claims 3-7, 9, 10, 13-17 and 19 as presented herein above.

If any further amendment to this application is believed necessary to advance prosecution and place this case in allowable form, the Examiner is courteously solicited to contact the undersigned representative of the Applicant to discuss the same.

In view of the above amendments and remarks, it is respectfully submitted that all of the raised rejection(s) should be withdrawn at this time. If the Examiner disagrees with the Applicant's view concerning the withdrawal of the outstanding rejection(s) or applicability of the Agdanowski et al. `398 and/or Kahn et al. `807 references, the Applicant respectfully requests the Examiner to indicate the specific passage or passages, or the drawing or drawings, which contain the necessary teaching, suggestion and/or disclosure required by case law. As such teaching, suggestion and/or disclosure is not present in the applied references, the raised

rejection should be withdrawn at this time. Alternatively, if the Examiner is relying on his/her expertise in this field, the Applicant respectfully requests the Examiner to enter an affidavit substantiating the Examiner's position so that suitable contradictory evidence can be entered in this case by the Applicant.

In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time,

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In view of the foregoing, it is respectfully submitted that the raised rejection(s) should be withdrawn and this application is now placed in a condition for allowance. Action to that end, in the form of an early Notice of Allowance, is courteously solicited by the Applicant at this time.

The Applicant respectfully requests that any outstanding objection(s) or requirement(s), as to the form of this application, be held in abeyance until allowable subject matter is indicated for this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

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